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April 21, 2004 by Kay Bulen Kay Bulen
Date Signature Printed Name

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Clinton et al.
Serial No.:	09/506,079
Filed:	February 16, 2000
For:	HER-2 BINDING ANTAGONISTS
Art Unit:	1642
Examiner:	Anne L. Holleran
Docket No.:	49321-16
Date:	April 21, 2004

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to the requirements in 37 C.F.R. § 1.56, and in conformance with 37 C.F.R. 1.97 and 1.98, Applicants hereby submit an Information Disclosure Statement. Applicants respectfully request that the Examiner: (1) consider the following documents during the course of her examination of the above-identified patent application, and (2) list the following documents in the References Cited section of any patent that may issue from the above-identified patent application.

As authorized by Examiner Holleran by voice mail on April 7, 2004, all cited references are provided, except U.S. patents and U.S. and WO patent applications, along with a completed Supplemental Information Disclosure Statement by Applicant listing form (formerly 1449).

One or more of these documents came to the attention of the Applicants when it was cited either in an International Search Report, a Supplemental European Search Report, or in the context of due diligence activities by potential investors evaluating the exclusive licensee of this application. (Copies of the corresponding Search Reports are enclosed.)

Applicants add the following comments relating to particular references:

WO91/02062 to Triton Biosciences Inc.

This PCT application claims priority to 04 August 1989, and claims DNA encoding, and polypeptides corresponding to gp75, which is the extracellular domain (ECD) of the c-erbB-2 (HER-2) receptor. Also claimed are anti-gp75 antibodies, methods of treatment and detection using anti-gp75 antibodies, and diagnostic assays based on detection of gp75. Use of gp75 polypeptides in vaccines is further claimed.

Significantly, WO91/02062 does not teach the novel ligands of this invention, and certainly does not describe or otherwise suggest the instant novel nucleic acids, proteins and polypeptides, compositions, methods and uses relating to applicants' inventive Herstatin (in fact, WO91/02062, at page 5, lines 4-7 states, as generally appreciated in the art at the time, that no ligand [agonist or antagonist] had been identified for the c-erb-2 receptor.).

WO01/89566 to Genentech, Inc.

This PCT application claims priority to 19 May 2000, and teaches and claims an assay to increase the likelihood of the effectiveness of an administered erbB antagonist cancer treatment (*i.e.*, anti-erbB antibodies; *e.g.*, Herceptin) to a subject having an amplified erbB gene in tumor cells from a tissue sample from that subject.

Significantly, with respect to c-erbB-2 (HER-2), WO01/89566, teaches only a method for increasing the likelihood of the effectiveness of an ErbB antagonist cancer treatment and specifically anti-HER-2 antibodies, and does not teach, describe or otherwise suggest the novel ligands of this invention, and certainly not the instant novel nucleic acids, proteins and polypeptides, compositions, methods and uses relating to applicants' inventive Herstatin (in fact,

WO01/89566, as revealed under the definition of 'ErbB ligand' at page 8, line 20 through page 9, and as generally appreciated in the art, teaches that no ligand [agonists or antagonists] had been identified for the c-erb-2 receptor.).

WO 95/25166 to New York University Medical Center

This PCT application claims priority (through CIP) to 1994, and claims proteins or peptides having a BLM domain, drug screening methods to identify binding partners to a BLM domain, and methods of treating, comprising the step of disrupting the interaction between a "BLM domain (See pages 24 through 26) and its natural binding partner," or between "domain 1 and/or domain 3 of an EGF receptor and an EGF ligand."

Significantly, WO95/25166 is directed to proteins or compositions having a BLM domain, drug screening methods to identify binding partners to a BLM domain, and methods of treating, comprising the step of disrupting the interaction between a BLM domain and its natural binding partner. , WO95/25166 neither teaches nor describes the novel ligands of this invention, and certainly does not teach, describe or otherwise suggest the instant novel nucleic acids, proteins and polypeptides, compositions, methods and uses relating to applicants' inventive Herstatin.

U.S. Patent 5,837,523 to Greene & Quain.

This patent claims priority (through CIP) to 1994, and claims a "nucleic acid molecule that encodes a protein that can form a dimer with epidermal growth factor receptor, and can form a dimer with p185 [HER-2], wherein said protein lacks tyrosine kinase activity...."

Significantly, U.S. 5,837,523 teaches the use of truncated or mutant p185 molecules that lack kinase activity and yet dimerize. U.S. 5,837,523 does not teach, describe or otherwise suggest the novel ligands of this invention, and does not teach, describe or suggest the instant novel nucleic acids, proteins and polypeptides, compositions, methods and uses relating to applicants' inventive Herstatin.

U.S. Patent 6,045,797 to Margolis & Schlessinger

This patent claims priority (through continuations) to 1994, and claims isolated polypeptides consisting of a BLM domain consisting of an amino acid sequence having at least

20% or 30% sequence identity to a specific amino acid sequence from GRB-7 protein. This subject matter is one aspect of the subject matter described in WO 95/25166 to New York University Medical Center, and like WO/95/251666, does not teach, describe or otherwise suggest the novel ligands of this invention and does not teach, describe or suggest the instant novel nucleic acids, proteins and polypeptides, compositions, methods and uses relating to applicants' inventive Herstatin.

U.S. Patent 5,985,553 to King et al.

This patent claims priority through continuations to 1987, and through CIP to 1986, and claims a nucleic acid that specifically hybridizes to at least part of a MAC117 gene [SEQ ID NO:2 of this patent] or nucleic acid derivate thereof, and which does not hybridize to a nucleic acid encoding EGF receptor under stringent conditions.

King et al., do not teach, describe or otherwise suggest the novel ligands of this invention and does not teach, describe or suggest the instant novel nucleic acids, proteins and polypeptides, compositions, methods and uses relating to applicants' inventive Herstatin.

The order of these references, or the inclusion of any comments thereon, should not be construed to suggest their relative pertinence. The filing of this Information Disclosure Statement should not be construed to suggest that a patentability search has been made or that the cited references are prior art or are considered to be material to patentability.

Applicants respectfully request consideration of the foregoing documents during examination of the above-identified patent application.

Respectfully submitted,

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 6

Complete if Known	
Application Number	09/506,079
Filing Date	February 16, 2000
First Named Inventor	Clinton
Art Unit	1642
Examiner Name	Anne L. Holleran
Attorney Docket Number	49321-16

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number-Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
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Examiner Signature		Date Considered	

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Sheet	5	of	6		

Complete if Known	
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Filing Date	February 16, 2000
First Named Inventor	Clinton
Art Unit	1642
Examiner Name	Anne L. Holleran
Attorney Docket Number	49321-16

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
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